

## REMARKS

The present amendment places the application in condition for allowance or in better form for appeal. Therefore, in accordance with the Manual of Patent Examining Procedure § 714.12, Applicants respectfully request that the present amendment be entered.

Upon entry of the present amendment, claims 36-53 will be pending. Claim 44 has been withdrawn by the Examiner in the final Office Action. Claims 36-42 and 44-53 have been amended. Support for the amendments can be found throughout the specification as filed, e.g., at page 10, first full paragraph. Claims 51 and 52 have also been amended to correct grammatical informalities. Applicants submit that no new matter has been added.

### Rejections under 35 U.S.C. § 112, First Paragraph

#### *Enablement Rejections*

The Examiner rejected claims 36-43 and 45-53 as allegedly not enabled (at pages 2-3 of the Office Action). Applicants respectfully disagree that the claims presented in the previous response were not enabled. Nonetheless, solely in the interest of expediting prosecution, Applicants have amended the claims to recite methods of producing starch, the methods comprising, *inter alia*, stably transforming a potato plant with at least a first and a second antisense heterologous nucleic acid sequence, wherein the first nucleic acid sequence encodes a potato starch synthase II (SSII) enzyme and the second nucleic acid sequence encodes a potato starch synthase III (SSIII) enzyme. The claims have also been amended to recite plants that comprise at least a first and a second heterologous nucleic acid antisense sequence, wherein the first nucleic acid sequence encodes a potato SSII enzyme and the second nucleic acid sequence encodes a potato SSIII enzyme. The specification fully enables skilled practitioners *to make and use* the claimed methods, plants, and starches.

The specification gives ample examples of how *to make* the claimed starches and plants, and how to carry out the claimed methods. For example, at pages 16-22, Example 1 describes one embodiment of transforming potato plants with antisense potato SSII and SSIII, followed by extracting and analyzing starch from the transformed plants.

Further, the specification enables those skilled in the art *to use* the claimed starches, plants, and methods. For example, according to the specification at page 4, second full paragraph, during use, starches obtainable by the claimed methods and from the claimed plants (e.g., starches having a reduced viscosity onset temperature) could be processed with reduced energy and under milder processing conditions. Moreover, use of potato starches as food products was well known in the art at the time of filing the application (see, e.g., “Field of the Invention” of the specification at page 1). Thus, skilled artisans could use the starches of the present invention to formulate a food product without undue experimentation. At least for the reasons stated above, Applicants submit that currently amended claims are fully enabled by the specification.

Moreover and importantly, at page 6 of the Office Action, the Examiner concedes that “Applicants have disclosed **antisense** constructs of **potato starch synthase II** and **potato starch synthase III** that when transformed into **potato**, yield the starch properties claimed by Applicants” (emphases in the original). The pending claims therefore fully comply with the enablement requirement. For the sake of completeness, Applicants address the Office’s nonenablement arguments as they relate to the currently amended claims.

The Action refers to at least three articles in support of the nonenablement rejection: Patron *et al.*, *Plant Physiol.* 130:190-98, 2002 (“Patron”); Edwards *et al.*, *Plant Cell* 14:1767-85, 2002; and Salehuzzaman/Shah *et al.*, *Plant Cell Environment* 22:1311-18, 1999 (“Salehuzzaman”). According to the Examiner at page 3,

Patron . . . reveals that different mutations in starch synthase result in differing amounts of amylose, and thus, result in unpredictable starch content, and therefore, unpredictable starch structure (see page 190 1<sup>st</sup> full paragraph, page 191, last full paragraph, page 192, last full paragraph). Furthermore, the breadth of the claims of the present invention would read on different isoforms of GBSSI, as a granule-bound starch synthase, is still a starch synthase and therefore encompassed by the breadth of the claims. Therefore, the unpredictability cited by Edwards *et al.*, namely the disclosure of the characterization of the discrete forms of amylose produced by different isoforms of GBSSI in pea (see page 1767, last full paragraph, page 1768 1<sup>st</sup> and second full paragraphs, page 1771 3<sup>rd</sup> full paragraph, and page 1775 in its entirety), is directly applicable to the current claims.

Without conceding the argument, but solely in the interest of expediting prosecution, the pending claims have been amended to recite methods, starches, and plants produced using nucleic acid

sequences encoding potato SSII enzyme and potato SSIII enzyme. In contrast, Patron and Edwards focus on studies and analysis of granule-bound synthase I (GBSSI) in barley and pea, respectively. Patron discusses low-amylose barley mutants of GBSSI and mentions GBSSI from potato (*Solanum tuberosum*) (at page 196, throughout). Edwards analyzes amylose synthesized by two isoforms of pea GBSSI that were expressed in a potato (at page 1768, second col.). Neither reference discusses methods, starches, or plants produced using nucleic acid sequences encoding potato SSII enzyme and potato SSIII enzyme, according to the presently amended claims. The Office has not shown otherwise. Therefore, neither Patron nor Edwards can serve as a basis for a nonenablement rejection of the present claims.

Further, the Office propounds at page 5 that:

the unpredictable starch content as a result of transforming a plant with a single gene is evidence of the unpredictable nature of transforming plants with heterologous starch synthase genes. The cassava GBSSI gene disclosed by Salehuzzaman is heterologous starch synthase gene and is encompassed by the claims as currently written.

The instant claims have been amended, as discussed above. Salehuzzaman is not relevant to the amended claims. Salehuzzaman analyzes cassava GBSSI gene for its ability to produce amylose in amylose-free potato mutants (see, e.g., Abstract). As such, the reference is not relevant to the current claims that recite methods, starches and plants produced using nucleic acid sequences encoding potato SSII enzyme and potato SSIII enzyme.

The Examiner also argues that “the art has many examples of unpredictability associated with starch content and transgenic plants” (at page 5) and cites Patron, Edwards, and Salehuzzaman in support of this contention. As discussed *supra*, the claims have been amended to recite a specific combination of potato starch enzymes, namely potato SSII and potato SSIII. The specification provides clear examples of transforming potato plants with this combination of antisense nucleic acids and obtaining starch with specific properties (see, e.g., Example 1 at pages 16-22). Thus, the claimed methods, starches, and plants are fully enabled by the specification.

Further according to the Examiner at page 4,

even in the case of claim 53, where potato starch synthase II and potato starch synthase III are specified, there are multiple embodiments of sequences that

would be classified as potato starch synthase II and potato starch synthase III. Absent a SEQ ID NO, limiting these DNA sequences to a particular sequence, any unpredictability associated with starch resulting from different sequences encoding the same enzyme directly apply to the claims.

Applicants respectfully disagree and submit that this statement takes official notice without substantiating documentary evidence. According to MPEP § 2144.03 A:

Official notice without documentary evidence to support an examiner's conclusion is permissible only in some circumstances. While "official notice" may be relied on, these circumstances should be rare when an application is under final rejection or action under 37 C.F.R. 1.113. Official notice unsupported by documentary evidence should only be taken by the examiner where the facts asserted to be well-known, or to be common knowledge in the art are capable of instant and unquestionable demonstration as being well-known.

Here, no evidence has been provided to support multiple embodiments of potato SSII and SSIII sequences and the alleged unpredictability associated with such embodiments. Further, a skilled practitioner would understand which sequences would constitute potato SSII and SSIII, given both the species and the isoform designations. The specification provides Accession Numbers for the sequences that were used in Example 1 (see, e.g., page 17, sections a) and b)), and those skilled in the art would similarly be able to find sequences and references relevant to potato SSII and SSIII in the public database. Thus, because the claimed nucleotide sequences are clearly identified, the present claims are fully enabled.

At least for the reasons presented above, withdrawal of all enablement rejections is respectfully requested.

#### *Written Description Rejections*

The Examiner rejected claims 36-43 and 45-53 as allegedly failing to comply with the written description requirement (at page 6). Applicants disagree that previously presented claims lacked written description. Nonetheless, to expedite prosecution, the claims have been amended as discussed above. The amended claims that recite methods, starches, and plants utilizing/with, *inter alia*, nucleic acid sequences encoding a potato SSII enzyme and a potato SSIII enzyme fully comply with the written description requirement. A skilled practitioner would understand that the Applicants were in possession of the claimed embodiments, because the specification provides examples of transforming plants with nucleic acids encoding potato synthase II and

potato synthase III and obtaining starch from such plants (see, e.g., Example 1, sections B) and C) at pages 16-18 of the specification as filed). The Examiner concedes at page 7 that “the described list [in the specification] only provides examples of functional equivalents of starch synthase II and starch synthase III.” Applicants submit that claims 36-43 and 45-53 (as well as withdrawn claim 44) comply with the written description requirement and respectfully request that all written description rejections be withdrawn.

Rejections under 35 U.S.C. § 102(b)

Claims 36-42 and 45-52 were rejected as allegedly anticipated by Block *et al.*, WO97/45545 (“Block”) (at page 8 of the Office Action). Applicants disagree that previously pending claims were anticipated by Block. Solely in the interest of expediting prosecution, the claims have been amended as discussed *supra*. The present claims are not anticipated by Block.

According to the Office at page 9,

Block discloses genetic constructs comprising altered nucleic acids that encode enzymes with starch synthase activity and disclose the alteration of starch content (see paragraph three, pages 5-7 through the middle of page 7, page 13 second paragraph, page 13 last paragraph, page 14 in its entirety, page 15 first paragraph, page 16 first paragraph, page 28 last half page, page 29 in its entirety, for example). Block *et al.* state “Moreover, the present invention also relates to transgenic plant cells transformed with **one or more** nucleic acid molecules of the invention” (see page 13 last paragraph). The nucleic acid molecules of the invention include GBSSI, GBSSII as well as soluble starch synthases (emphasis in the original).

Applicants submit that Block does not anticipate presently amended claims or the claims presented previously. As discussed above, the claims have been amended to recite methods, starches, and plants utilizing/with, *inter alia*, nucleic acid sequences encoding a potato SSII enzyme and a potato SSIII enzyme. Block does not appear to teach a potato starch synthase III enzyme. The Office has not shown otherwise. For example, while Block mentions soluble starch synthases in general (at page 3, second full paragraph), the reference only lists the following enzymes involved in starch biosynthesis: GBSSI, GBSSII, soluble starch synthase I, soluble starch synthase II, branching enzymes, debranching enzymes, disproportionizing enzymes, and starch phosphorylases (see, e.g., Block at page 31, second full paragraph). Thus, Block does not mention starch synthase III. Further, Block focuses on plants and methods that

involve wheat synthases. For example, Block states that “it was the object of the present invention to provide nucleic acid molecules encoding enzymes – especially enzymes from wheat – involved in starch biosynthesis” (Block at page 5; emphasis added). Therefore, because Block does not teach potato starch synthase III, one of the elements of the present claims, Block does not anticipate the present claims. Withdrawal of all anticipation rejections is respectfully requested.

Rejections under 35 U.S.C. § 103(a)

The Examiner rejected claims 36-42 and 45-53 as allegedly being obvious in view of Block (at page 9). According to the Examiner at page 10:

Block et al. discloses genetic constructs comprising altered nucleic acids that encode enzymes with starch synthase activity and disclose the alteration of starch content (see paragraph three, pages 5-7 through the middle of page 7, page 13 second paragraph, page 13 last paragraph, page 14 in its entirety, page 15 first paragraph, page 16 first paragraph, page 28 last half of page, page 29 in its entirety, for example). Block et al state “Moreover, the present invention also relates to transgenic plant cells transformed with **one or more** nucleic acid molecules of the invention” (see page 13 last paragraph). The nucleic acid molecules of the invention include GBSSI, GBSSII as well as soluble starch synthases. Furthermore Block discloses . . . “Compared with wild-type starch, such starch may be modified in particular with respect to its viscosity and/or the gel formation properties of the glues of this starch” (emphasis in the original).

Applicants disagree that Block renders presently amended claims (or previously presented claims) obvious. Block does not teach or suggest the claimed combination of elements and does not show that the results of the combination would be predictable. The Examiner has not shown otherwise and has not established a *prima facie* case of obviousness.

The current claims are drawn to methods, starches, and plants that include, *inter alia*, nucleic acid sequences encoding a potato SSII enzyme and a potato SSIII enzyme. As discussed above, Block does not teach the potato synthase III element of the present claims, and therefore does not teach or suggest the specifically claimed combination of SSII and SSIII nucleic acid sequences.

Further, the results of the claimed combination were not predictable from Block. Using this specific combination,

the present inventors have surprisingly found that starch extracted from a plant transformed by introduction of an SSII/SSIII combination operably linked in the antisense orientation to a suitable promoter according to the invention, or the progeny of such a plant, has a viscosity onset temperature, as determined by viscoamylograph, which is significantly reduced compared to the effects predicted by reducing the two isoforms individually or to equivalent, unmodified plants (specification at page 10; emphases added).

Thus, Block's general mention of viscosity modification (cited by the Examiner in the quote above) would not have led a skilled practitioner to predict the results of the potato SSII/SSIII combination. As the specification states, the resulting reduction in the viscosity temperature was not predictable from reduction of each enzyme of the combination. Moreover, according to the specification at page 2, "[t]he role of each isoform in the control of starch synthesis and structure is unclear at present since the contribution of each isoform to the total activity varies considerably between species" (emphasis added). As discussed above, Block focuses on wheat enzymes and therefore does not provide a teaching that would have motivated a skilled practitioner to combine the nucleic acids encoding potato SSII and SSIII in a potato plant to arrive at starches with the specific claimed properties.

Because Block does not teach or suggest the claimed combination of elements and does not show that the results of the combination would be predictable, it cannot serve as a basis for an obviousness rejection of the present claims. Withdrawal of all obviousness rejections is respectfully requested.

**CONCLUSION**

It is respectfully submitted that the above-identified application is now in a condition for allowance and favourable reconsideration and prompt allowance of these claims are respectfully requested. Should the Examiner believe that anything further is desirable in order to place the application in better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

The Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 (with the exception of the issue fee) which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 50-1283. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. § 1.136(a)(3).

Dated: January 8, 2008

Customer Number: 58249  
COOLEY GODWARD KRONISH LLP  
ATTN: Patent Group  
777 6<sup>th</sup> Street NW, Suite 1100  
Washington, DC 20001

Tel: (202) 842-7800  
Fax: (202) 842-7899

Respectfully submitted,  
**COOLEY GODWARD KRONISH LLP**

By: Anna Soloniz REG. NO.: 54,093  
for: Erich E. Veitenheimer  
Reg. No. 40,420